

What we claim is:

1. A pharmaceutical composition of gabapentin wherein lactam level remains below 0.5 % w/w after at least 2 years of storage at 25 °C and 60% relative humidity.
- 5 2. A pharmaceutical composition of gabapentin wherein lactam level remains below 0.5% w/w after at least 2 years storage at 30 °C and 60% relative humidity.
3. A pharmaceutical composition of gabapentin wherein lactam level remains below 0.5% w/w after at least 6 months storage at 40 °C and 75% relative humidity.
- 10 4. A pharmaceutical composition of gabapentin comprising less than 0.5% w/w of lactam after storage conditions selected from the ranges consisting of: storage for at least 3 years at 25°C and 60% relative humidity, storage for at least 2 years at 25 to 30°C and 60% relative humidity, and storage for at least 6 months at 40°C and 75% relative humidity.
- 15 5. The pharmaceutical composition according to Claim 4, further comprising at least one excipient selected from the group consisting of dibasic calcium phosphate, tribasic calcium phosphate, calcium sulphate, mannitol, microcrystalline cellulose, starch IP, lactose, magnesium stearate, steric acid, colloidal silicon dioxide and sodium lauryl sulphate.
- 20 6. The pharmaceutical composition according to Claim 5, comprising microcrystalline cellulose as the excipient.
- 25 7. The pharmaceutical composition according to Claim 5, comprising magnesium stearate and microcrystalline cellulose as excipients.
8. The pharmaceutical composition according to Claim 4, further comprising one or more of a diluent, a lubricant and a solubilizer.
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9. The pharmaceutical composition according to claim 8, comprising at least one diluent selected from the group consisting of dibasic calcium phosphate, tribasic calcium phosphate, calcium sulphate, mannitol, microcrystalline cellulose, starch IP and lactose.
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10. The pharmaceutical composition according to Claim 8, comprising at least one lubricant selected from the group consisting of magnesium stearate, steric acid or colloidal silicon dioxide.
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11. The pharmaceutical composition according to Claim 8, comprising sodium lauryl sulphate as solubilizer.
12. The pharmaceutical composition according to Claim 8, comprising microcrystalline cellulose as diluent.
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13. The pharmaceutical composition according to Claim 8, comprising magnesium stearate as lubricant.
14. The pharmaceutical composition according to Claim 8, comprising microcrystalline cellulose as diluent and magnesium stearate as lubricant.
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15. The pharmaceutical composition according to Claim 8, comprising the composition in the form of a capsule for oral use.
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16. The pharmaceutical composition according to Claim 15, wherein the capsule comprises hard gelatin.
17. The capsule according to Claim 16, further comprising at least one additive selected from the group consisting of methyl hydroxyl benzoate, propyl hydroxyl benzoate, titanium oxide, yellow iron oxide, and red iron oxide, in any suitable combination.
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18. The pharmaceutical composition according to Claim 4, wherein the stability of gabapentin is independent of the mineral acid anion content.
19. The pharmaceutical composition according Claim18, wherein the content of mineral acid anion is less than 70 ppm.
20. The pharmaceutical composition according to Claim18, wherein the content of mineral acid anion is less than 50 ppm.
21. The pharmaceutical composition according to Claim 18, wherein the content of mineral acid anion is less than 30 ppm.
22. The pharmaceutical composition of Claim 18, wherein the content of the mineral acid is in the range of 20 to 70 ppm.
23. The pharmaceutical composition of Claim 18, wherein the content of the mineral acid is in the range of 20 to 50 ppm.
24. The pharmaceutical composition of Claim 18, wherein the content of the mineral acid is in the range of 20 to 30 ppm.